AF/2172

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/682,098
Applicants	:	BERNHART ET AL.
Filed	:	JULY 19, 2001
Title	:	SYSTEM, METHOD, AND COMPUTER PROGRAM PRODUCT FOR MANAGEMENT OF BIOLOGICAL EXPERIMENT INFORMATION
Art Unit	:	2172
Examiner	:	BAOQUOC N. TO
Atty Docket No.	:	AFFY-0016-8 (FORMERLY 3348.2)

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF TRANSMITTAL LETTER

Sir:

The below-identified communication(s) is (are) submitted in the above-captioned application or proceeding:

☒ Appellant's Brief on Appeal (27 pages, in triplicate)

☒ Patent Fee Transmittal for FY 2005 (one (1) page, in duplicate)

Respectfully submitted,

Michael G. Verga, Esq.
Registration Number 39,410

JAGTIANI + GUTTAG
Democracy Square Business Center
10363-A Democracy Lane
Fairfax, Virginia 22030
(703) 591-2664

December 8, 2004

Patent Fee Transmittal for FY 2005

☐ Applicant Claims Small Entity Status 37 C.F.R. 1.27

TOTAL AMOUNT OF PAYMENT	$500.00

*** *Includes fee changes from HR 4818, Sec. 801, signed on December 8, 2004*

Application Number	09/682,098
Filing Date	19-Jul-01
Named Inventor	Bernhart, et al.
Examiner Name	Baoquoc N. To
Art Unit	2172
Attorney Docket No.	AFFY-0016-8

FEE CALCULATION

1. Filing Fees

Application Type		Description	Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
Utility	☐	Basic	1011	300	2011	150	$ -
		Examination	1311	200	2311	100	$ -
		Search	1111	500	2111	250	$ -
Design	☐	Basic	1012	200	2012	100	$ -
		Examination	1312	130	2312	65	$ -
		Search	1112	100	2112	50	$ -
Plant	☐	Basic	1013	200	2013	100	$ -
		Examination	1313	160	2313	80	$ -
		Search	1113	300	2113	150	$ -
Reissue	☐	Basic	1014	300	2014	150	$ -
		Examination	1114	600	2114	300	$ -
		Search	1314	500	2314	250	$ -
National Stage	☐	Basic	1631	300	2631	150	$ -
		Examination	1633	200	2633	100	$ -
		Search	1632	500	2632	250	$ -
Provisional	☐	Basic	1005	200	2005	100	$ -

2. Extra Claim Fee

a. Claims as Filed

					Extra Claims		Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
Total Claims	0	- 20 =	0	x			1201	50	2201	25	$ -
Independent	0	- 3 =	0	x			1202	200	2202	100	$ -
Multiple Dependent							1203	360	2203	180	$ -

b. Claims as Amended

	After Amnt		Highest Paid		Present Extra		Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
Total Claims	0	-	0	* =	0	x	1201	50	2201	25	$ -
Independent	0	-	0	** =	0	x	1202	200	2202	100	$ -
First Presentation of Multiple Dependent							1203	360	2203	180	$ -

* Less than 20, enter 20 ** Less than 3, enter 3

3. Extra Page Fee

Total Pages		Extra Pages		Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
0	-100	0	x	1081	250	2081	125	$ -

Subtotal for Application Fees

1 $ - + 2 $ - + 3 $ - = $ -

4. Additional Fees

Description	Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
Extension for response first month	1251	120	2251	60	$ -
Extension for response second month	1252	450	2252	225	$ -
Extension for response third month	1253	1,020	2253	510	$ -
Extension for response fourth month	1254	1,590	2254	795	$ -
Extension for response fifth month	1255	2,160	2255	1,080	$ -
Notice of Appeal	1401	500	2401	250	$ -
Filing a Brief in Support of an Appeal	1402	500	2402	250	$ 500
Request for Oral hearing	1403	1,000	2403	500	$ -
Petitions under 1.17(f)	1462	400	1462	400	$ -
Petitions under 1.17(g)	1463	200	1463	200	$ -
Petitions under 1.17(h)	1464	130	1464	130	$ -
Petition - public use proceeding	1451	1,510	1451	1,510	$ -
Petition to Revive - Unavoidable	1452	500	2452	250	$ -
Petition to Revive - Unintentional	1453	1,500	2453	750	$ -
Utility Issue Fee	1501	1,400	2501	700	$ -
Design Issue Fee	1502	800	2502	400	$ -
Plant Issue Fee	1503	1,100	2503	550	$ -
Reissue Issue Fee	1511	1,400	2511	700	$ -
Publication Fee	1504	300	1504	300	$ -
Statutory Disclaimer	1814	130	2814	65	$ -

(cont.)

Description (cont.)	Large Entity Code	Large Entity ($)	Small Entity Code	Small Entity ($)	Paid
Recording each Assignment	8021	40	8021	40	$ -
Submission of IDS	1806	180	1806	180	$ -
Request for Cont. Examination (RCE)	1801	790	2801	395	$ -
Filing Submission After Final	1809	790	2809	395	$ -
Surcharge - late filing fee or oath	1051	130	2051	65	$ -
Surcharge - late provisional fee	1052	50	2052	25	$ -
Non-English Specification	1053	130	1053	130	$ -
Processing Fee 37 CFR 1.17(q)	1807	50	1807	50	$ -
Request for *Ex Parte* Reexamination	1812	2,520	1812	2,520	$ -
Request Pub. of SIR prior to action	1804	920	1804	920	$ -
Request Pub. of SIR after action	1805	1,840	1805	1,840	$ -
Each Add. Invention Examined	1810	790	2810	395	$ -
Expedited Examination (Design)	1802	900	1802	900	$ -
Unintentionally Delayed Priority Claim	1453	1,370	1453	1,370	$ -
Certificate of Correction	1811	100	1811	100	$ -
Maintenance Fees 3.5 years	1551	900	2551	450	$ -
Maintenance Fees 7.5 years	1552	2,300	2552	1,150	$ -
Maintenance Fees 11.5 years	1553	3,800	2553	1,900	$ -
Surcharge - Late Payment 6 mos.	1554	130	2554	65	$ -
Other fee _____					$ -

Additional Fee Subtotal $ 500

METHOD OF PAYMENT

☑ Deposit Account No. **10-0233-AFFY-0016-8**

☑ The Commissioner is hereby authorized to charge the amount shown above and any additional fees which may be required under 37 CFR 1.16, 1.17, 1.18, 1.20 and 1.492 or credit any overpayment to the deposit account number listed above.

Name	Michael Verga	Reg. No.	39,410
Firm	Jagtiani + Guttag		
Address	10363-A Democracy Lane, Fairfax VA 22030		
Telephone	703.591.2664	Fax	703.591.5907

Signature

December 8, 2004
Date

Revised 12-2004

Include duplicate copy if paying by deposit account

PATENT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the Application of:	Derek BERNHART *et al.*
Serial No.:	09/682,098
Filed:	July 19, 2001
Entitled:	SYSTEM, METHOD, AND COMPUTER PROGRAM PRODUCT FOR MANAGEMENT OF BIOLOGICAL EXPERIMENT INFORMATION
Docket No.:	AFFY-0016-8 (FORMERLY 3348.2)

Group Art Unit: 2172

Examiner: Baoquoc N. TO

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 1.192

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Affymetrix, Inc. of Santa Clara, California ("Affymetrix"). Affymetrix derives its rights in the captioned application by virtue of an assignment of the application by the inventors to Affymetrix, Inc.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-44 are currently pending in the present application, application number 09/682,098. According to the Final Office Action mailed on April 8, 2004, and the Advisory Action mailed August 13, 2004, claims 1-19 and 29-38 stand finally rejected under 35 USC 103(a) as being unpatentable over U.S. Patent No. 5,594,858 to Blevins (hereinafter "*Blevins*") in view of U.S. Patent No. 6,229,911 to Balaban *et al.* (hereinafter "*Balaban*"); and claims 20-28 and 39-44 stand finally rejected under 35 USC 103(a) as being unpatentable over *Blevins*. Accordingly, claims 1-44 are subject to appeal.

IV. STATUS OF AMENDMENTS

All amendments have been entered.

V. SUMMARY OF THE INVENTION

The present invention is directed to acquiring and managing data related to biological experiments such as data acquired by scanning images of probe arrays of biological materials. Figure 1 of Applicants' application, reproduced below, provides an overview of a typical procedure for preparing and using a laboratory probe array assay.

In step 110, a user 100 designs a research project involving different samples and experiments on which one or more researchers may cooperate. User 100 typically prepares a sample (step 120), sets up an experiment (step 130; e.g., makes further sample treatment, determines fluidics condition, and prepares reagents), and selects an appropriate probe array to

be used in an assay (step 140; e.g., synthesized, spotted, or other array or parallel biological assay). The prepared sample is then hybridized with the probe array, preferably in a hybridization oven (step 150) to allow binding of a target nucleic acid with a probe on the chip. The target-probe nucleic acid complex is fluorescently labeled (or otherwise labeled in other implementations; step 160). Other processing, such as washing, may also occur.

The probe array is introduced into a scanner to generate an image file indicating the locations where the labeled nucleic acids bound to the chip (step 180). The scanner images the targets by detecting fluorescent or other emissions from the labels, or by detecting transmitted, reflected, or scattered radiation. Based on the identities of the probes at these locations, it becomes possible to extract information such as the monomer sequence of DNA and the expression level of a specific target gene (step 190). Other information typically is provided to facilitate or enable analysis, such as data describing the probes used in the probe arrays (step 192). The analyzed result may be stored in a bioinformatics database managed by user 100 and administrator 105.

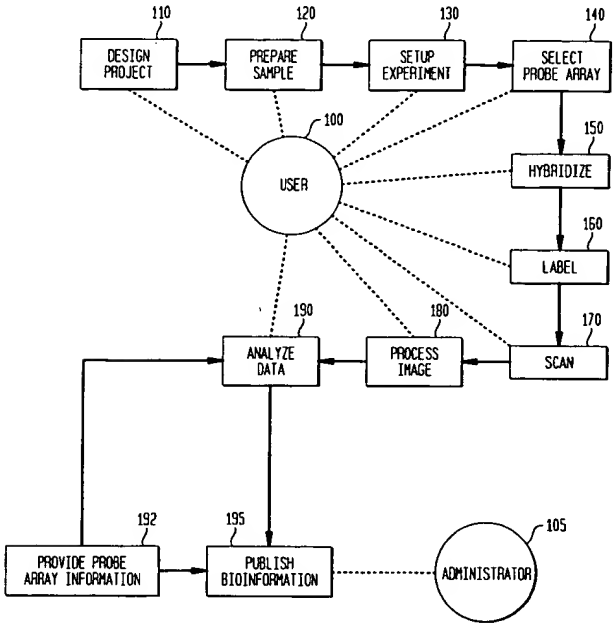

Figure 1 of Present Application

Figure 3 of Applicants' application, reproduced below, shows the data flow among an analysis application 300, library information management system (LIMS) application 311, and peripheral instruments and other devices. To facilitate understanding, this version of Figure 3 has been supplemented with reference numerals and data descriptors originally presented in the specification and/or other Figures of Applicants' application.

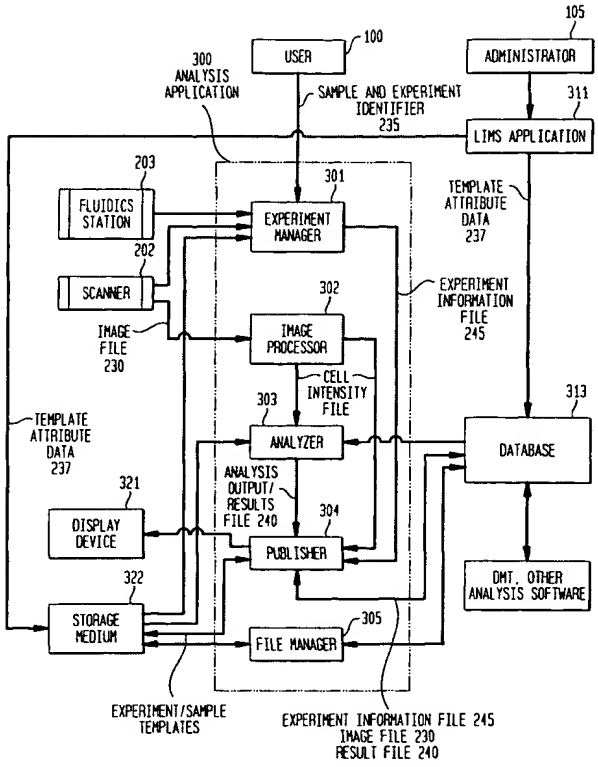

Figure 2 of Present Application

Prior to user 100 conducting projects or experiments, administrator 105 uses LIMS application 311 to generate template attribute data 237 specifying attributes for one or more experiment or sample identifiers. Analysis application 300 uses template attribute data 237 to generate experiment and/or sample templates by which a user enters values for each experiment identifier in accordance with the specified attributes. An exemplary experiment template is described below with reference to Applicants' Figure 4F. The generated templates are stored on storage medium 322 or elsewhere.

Analysis application 300 includes, in this example, an experiment manager 301, image processor 302, analyzer 303, publisher 304, and file manager 305. User 100 inputs sample and experiment identifiers 235 into experiment manager 301 according to a default table or a data template stored on storage medium 322, an example of which is described below with reference to Applicants' Figure 6. User 100 may set up fluidics protocol and scanning parameters using analysis application 300 so that fluidics station 203 and scanner 202 may be operated under the control of analysis application 300. Experiment manager 301 captures information about the fluidics protocol and scanning parameters after a probe array is processed in fluidics station 203

and is scanned in scanner 202. This information is processed and sent to publisher 304 as an experiment information file 245. Experiment information file 245 may be stored in a database 313 for further analysis using other analysis software. Publisher 304, under control of user 100, may also display information from experiment information file 245 on display device 321.

Image file 230 is generated by scanner 202 and sent to image processor 302 after scanner 202 scans a probe array. Intensity values for each probe cell are than calculated by image processor 302 according to cell analysis algorithms and are stored as a cell intensity file which is provided to publisher 304 for storage on the same storage medium where the experiment information file 245 is stored. Other authorized users may also read the file if it is stored on database 313.

The cell intensity file may be sent to analyzer 303, for example, for gene expression or genotype analysis. Analyzer 303 acquires probe array information from an electronically stored database. The analysis output file may be provided to publisher 304 and saved on the same storage medium where the experiment information file 245 is stored.

File manager 305 is designed to manage files derived from the biological experiments. Through file manager 305, user 100 may trace and find files for a specific biological project, sample, or experiment. File manager 305 may display the files on display device 321 according to the sample history, may show all complete or pending stages for a particular sample, or help user 100 monitor the experiment work flow. Accordingly, user 100 may easily manage the complicated experiment information of different research projects and experiments.

Figure 4F of the present application, reproduced below, shows an illustrative

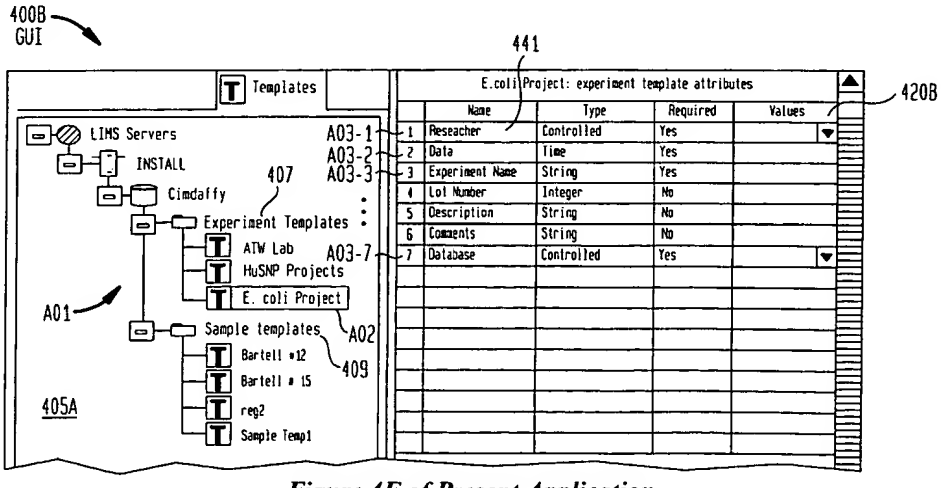

Figure 4F of Present Application

graphical user interface (GUI) 400F used by an administrator 105 to generate a new or modified experiment or sample template. To facilitate understanding, this version of Figure 4F includes additional reference numerals cited herein. GUI 400B includes a pane 405A that includes a tree data structure A01 listing available experiment templates 407 and sample templates 409. Administrator 105 may select an existing template to edit from the displayed lists, or create a new template. In the example shown, administrator 105 has selected an experiment template named "E. coli Projects" A02, which is depicted in pane 420B on the right side of display 400B.

The administrator 105 enters in data specifying one or more attributes for each of one or more identifiers A03. In the example shown in Figure 4F, there are seven (7) experiment identifiers, labeled A03-1 through A03-7. The attributes for each experiment identifier A03-N includes a name attribute, type attribute and a required attribute, each being allocated a column in this exemplary display. A set of one or more restrictive values for the attribute, which may be specified by administrator 105, is also provided in a similar column.

The administrator 105 provides a name attribute for each identifier. Taking experiment identifier A03-1 as an example, administrator 105 inputs the name attribute value "Researcher" in graphical element 441.

The data type attribute of each identifier may be defined by entering or selecting a choice from a drop-down list of "Type" column. Examples values for this attribute shown in Figure 4F include, for example, string, time integer, and controlled. For a controlled data type, acceptable values are limited to the items listed in a "Values" column drop-down list defined by administrator 105. One example mentioned in Applicants' application is that only researchers specified in the experiment template are authorized to access the experiment.

Collectively, the above information entered into GUI 400B is referred to as template attribute data 237. Once the template attribute data 237 defining identifiers A03 have been entered by administrator 105, the administrator signifies the completion of this task in accordance with any of a variety of conventional techniques, and template attribute data 237 corresponding to the entered data is stored in storage medium 322.

As noted in Applicants' specification, the attributes described in the application are illustrative only, and that administrator 105 may specify in experiment templates many other attributes relating to experiments and many other attributes relating to samples (i.e., to be used as targets in probe array assays) in sample templates. For example, other experiment or sample

attributes include factors such as concentration of the probe and target, time, temperature, cation concentration, valency and character, pH, dielectric and chaotropic media, and density spacing of the probe molecules synthesized on the surface.

The user enters values for sample and experiment identifiers into a data template generated using template attribute data 237, as noted above. In this example, the resulting experiment template 620 is illustrated in Figure 6 of Applicants' application, and reproduced below. The user 100 inputs data into the exemplary graphical display of experiment template 620, which is then included in experiment information file 245.

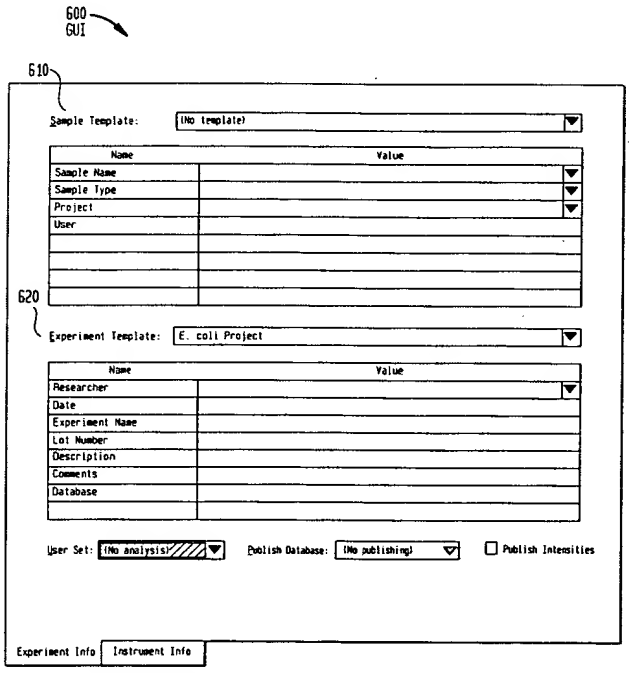

Figure 6 of Present Application

Advantageously, the sample and experiment information contained in experiment information files 245, image files 230 and results files 240, can be accessed by all authorized users. Traditionally, such information has been recorded in laboratory notes or in an isolated database, and is often difficult or inconvenient to share with others, preventing the association of sample and experiment identifiers file data with image data and analyzed results data. Also, many of the contemplated applications of probe arrays involve performing the above-described processing stages on a very large scale, resulting in a vast quantity of information to store and correlate. The present invention enables users to organize, access and analyze a large amount of

information generated and collected using probe arrays, as well as other information related to each probe array assay.

VI. ISSUES

1. Whether the Examiner improperly rejected claims 1-19 and 29-38 as being unpatentable over the combination of *Blevins* and *Balaban* when *Blevins* and *Balaban*, taken alone or in combination, fail to disclose, teach or suggest all limitations recited in the noted independent and dependent claims, in particular, including a method for managing biological information related to a biological experiment as recited in claim 1, and a computer program product as recited in independent claim 29.

2. Whether the Examiner improperly rejected claims 20-28 and 39-44 as being unpatentable over *Blevins* when *Blevins* fails to disclose, teach or suggest all limitations recited in the noted independent and dependent claims, in particular a method for managing biological experiment information generated through the performance of a biological experiment with probe arrays, as recited in claim 20, and a computer implemented system for managing information of probe array experiments, as recited in independent claim 39.

VII. GROUPING OF CLAIMS FOR THE PURPOSES OF THIS APPEAL

For reasons set out below, Applicants consider the following groups of claims to be separately patentable for the purposes of this Appeal only:

(a) Claim(s) 1-19 and 29-38; and

(b) Claim(s) 20-28 and 39-44.

VIII. ARGUMENT

A. OBVIOUSNESS REJECTIONS OF CLAIMS 1-19 AND 29-38

1. THE REJECTIONS

Claims 1-19 and 29-38 stand finally rejected under 35 USC 103(a) as being unpatentable over *Blevins* in view of *Balaban*. Specifically, the Examiner asserts that *Blevins* substantially teaches Applicants' invention as recited in independent claims 1 and 29. With regard to claim 1,

the Examiner asserts that *Blevins* teaches all method steps of the claim other than method step (a). With regard to claim 29, the Examiner asserts that *Blevins* teaches all elements other than a template generator as claimed. (*See*, April 8, 2004, Office Action, pgs. 3 and pg. 6.)

The Examiner acknowledges, however, that *Blevins* fails to teach "providing one or more identifier[s] related to the use of the probe array used to acquire the biological information" as recited in claim 1, and "a template generator that generates a data template including one or more identifiers of a biological experiment with probe arrays, each identifying an attribute of the experiment," as recited in claim 29. (*See*, April 8, 2004, Office Action, pgs. 5 and 7.)

The Examiner asserts that *Blevins* "teaches [that its] data prompts are the identifiers related to the project," and that *Balaban* teaches "creating a template for the experiment" and "the use of the probe array to obtain gene sequences." Based on these assertions, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to modify the probe array to obtain the gene expression into *Blevins* in order to create template and use the probe array to obtain gene expression to conduct the biological experiment." (*See*, April 8, 2004, Office Action, pg. 4, para 1.)

2. *BLEVINS* IS DIRECTED TO CREATING USER-SPECIFIC DISPLAYS FOR A PROCESS MONITORING AND CONTROL SYSTEM, NOT A METHOD FOR MANAGING BIOLOGICAL INFORMATION AS THE EXAMINER ASSERTS

Blevins does not teach that which the Examiner asserts and relies on in the rejection of independent claims 1 and 29. Applicants respectfully assert that the Examiner has misapprehended this reference, and traverse each of Examiner's contentions for the reasons set out below.

Blevins is directed to process monitoring and control systems and, in particular, to a system for creating control templates that have attributes, methods, and graphical views associated therewith that can be selected by a user to design process control solutions and from which a user can create a unique display of a view such as an engineer's view, operator's view, controller's view, and the like. (*See*, Blevins, col. 1, lns. 16-26.) Process control as defined in *Blevins* "involves the use of instruments, control devices and systems for measuring and manipulating control elements such as valves to maintain one or more process variables, such as

temperature, pressure and flow, at target values selected to achieve a desired objective of a process including the ... operation of machines and equipment utilized in the process. Process control systems have widespread application in the automation of industrial processes such as those used in chemical, petroleum, and manufacturing industries, for example." (*See*, Blevins, col. 1, lns. 29-39.)

Each of the engineers, maintenance personnel, operators, lab personnel and the like, require a graphical view of the elements of the process control system that enables them to view the system in terms relevant to their responsibilities. (*See*, Blevins, col. 2, lns. 14-17.) For example, to control a specific process control function an engineer uses an engineer's view of the process to adjust parameters used by implementing microprocessor-based controllers. (*See*, Blevins, col. 1, lns. 40-56.) Software programs are also used to provide feedback in the form of an operator's display or view regarding the status of particular processes, to signal an alarm when a problem occurs, or to provide instructions or suggestions to an operator when a problem occurs. The operator who is responsible for the control process needs to view the process from that person's point of view. This is because systems that perform, monitor, control, and feedback functions in process control environments are typically implemented by software written in high-level computer programming languages that are not usually used or understood by process engineers, maintenance engineers, control engineers, operators and supervisors. Higher level graphical display languages have been developed for such personnel, such as continuous function block and ladder logic. (*See*, Blevins, col. 2, lns. 3-14.)

Blevins observed that there is a need for a universal design environment that can easily be used, not only by a designer or manufacturer but also a user, to customize an existing solution to meet his/her specific needs for developing process control functions. (*See*, Blevins, col. 3, lns. 10-34.) An example of the *Blevins* system is illustrated in Figure 4 of *Blevins*, reproduced below.

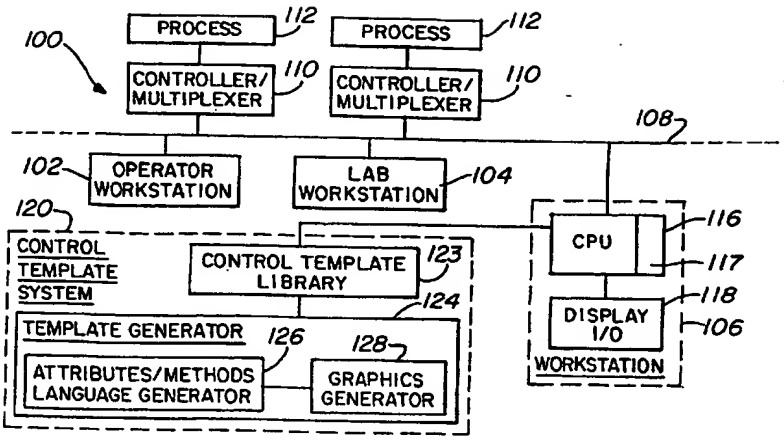

Figure 4 of Blevins

A process control environment 100 includes an operator workstation 102, a lab workstation 104, and an engineering workstation 106 interconnected to a plurality of the controller/multiplexers 110 that provide an electrical interface with plurality of processes 112 via a LAN 108. (*See*, Blevins, col. 5, ln. 24 – col. 6, ln. 6.)

A template generator 124 and the control template library 123 form a control template system 120. A control template according to *Blevins* "is defined as the grouping of attribute functions that are used in controlling a process and the methodology used for a particular process control function, the control attributes, variables, inputs, and outputs for the particular function and the graphical views of the function as needed such as an engineer view and an operator view." (*See,* Blevins, col. 7, lns. 10-17.)

Control template library 123 contains data representing sets of predefined or existing control template functions for use in process control programs. Template generator 124 provides an interface that allows a user to create new control template functions or modify existing control template functions, both of which may also be stored in the control template library 123. Template generator 124 includes an attributes and methods language generator 126 and a graphics generator 128. The attributes and methods language generator 126 provides display screens that allow the user to define a plurality of attribute functions associated with the creation of a new control template function or modification of a particular existing control template function, such as inputs, outputs, and other attributes, as well as providing display screens for enabling the user to select methods or programs that perform the new or modified function for

the particular control template. The graphics generator 128 provides the means for designing graphical views to be associated with particular control templates. A user utilizes the data stored by the attributes and methods language generator 126 and the graphics generator 128 to completely define the attributes, methods, and graphical views for a control template. (*See*, Blevins, col. 7, lns. 3-49.)

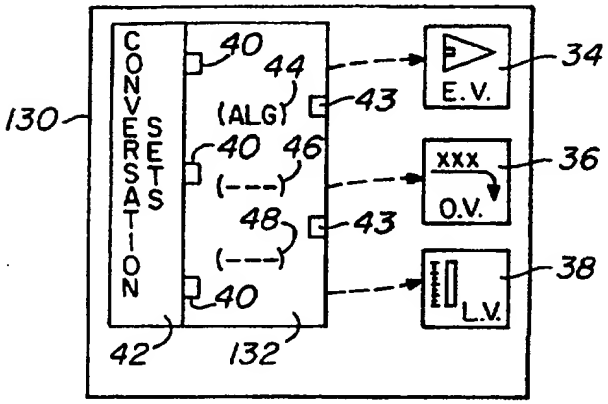

Figure 5A of Blevins

Figure 5A of *Blevins*, reproduced to the left, is an exemplary control template 130 including a process control function 132 designated with attributes such as inputs 40 and outputs 43. It includes the algorithm 44 necessary for performing the function and parameters 46 and 48 upon which the algorithm 44 may operate to utilize the inputs 40 and outputs 43 to provide the process control function desired. Conversation sets 42 are created and associated with the process control function 132. These conversation sets relate to the parameters of the process control function in terms of the engineer's view, the operator's view, the controller's view, the maintenance view and other views as desired. Control template views 34, 36, and 38 are shown created as a part of the process control template 130 and identified from the standpoint of an engineer's view, operator's view, and lab view. Control template views 34, 36, and 38 are stored in the control template library 123 where they can be selected by the user through the interface 118 to define control/monitor strategy at the engineer's workstation 106 or to create displays using predefined template views for operator or lab interfaces to the control/monitor strategy in the workstations 102 and 104. (*See*, Blevins, col. 7, ln. 50 – col. 8, ln. 34.)

3. THE EXAMINER'S REASONING IN MAKING THE OBVIOUSNESS REJECTION IS INCORRECT, LEAVING THE OFFICE ACTION WITHOUT A PRIMA FACIE REJECTION

As noted, the Examiner acknowledged that *Blevins* fails to teach providing one or more identifiers related to the use of a probe array used to acquire biological information, as recited in

claim 1. The Examiner provides the following series of contentions in an effort to support the assertion that one of ordinary skill in the art would have been motivated to modify *Blevins* with the teachings of *Balaban*.

- *Blevins* "teaches [that its] data prompts are the identifiers related to the project," relying on column 10, lines 1-5 of *Blevins*: "the selection portion 224 provides a list of data prompts related to processes associated with the particular project that may be selected by a user to create[] the unique control template or modify an existing control template."

- *Balaban* teaches "creating the template for the experiment." For this contention, the Examiner cites column 7, lines 56-61: "a template type associated with each protocol template indicates that kind template. The template type identifies, for example, whether the template identifies parameters for experiments, for analysis or for target preparation."

- *Balaban* teaches "the use of the probe array to obtain gene sequences." For this contention, the Examiner cites column 12, lines 11-55 of Balaban: "an analysis ID column identifies the analysis as listed in analysis table 438 that produced the relative gene expression result ... A positive pairs ratio column lists the ratio of the numbers of positive probe pair between two targets."

Based on these contentions, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to modify the probe array to obtain the gene expression into *Blevins* in order to create template and use the probe array to obtain gene expression to conduct the biological experiment." (*See*, Office Action, pg. 4.) Applicants respectfully traverse this rejection.

There is no motivation to combine the bioinformatics database teachings of *Balaban* with the teachings regarding control templates for process monitoring and control systems as taught by *Blevins*. The rationale for such a combination provided by the Examiner in the Final Office Action is that one would be motivated to "create [a] template and use the probe array to obtain the gene expression to conduct the biological experiment." This rationale is unclear, conclusory and unsupported by the art of record. *Blevins*, as noted, teaches providing user-specific views of a process monitoring and control system, not data templates as alleged by the Examiner, and certainly not as recited in Applicants' claims. *Balaban* teaches nothing more than a database for

bioinformatics data. Thus, there is no motivation to combine these references, let alone combine them in the manner proposed. That is, there is no suggestion to provide in *Blevins* a database as taught in *Balaban*, nor is there any suggestion to provide the user-specific view of *Blevins* in the database of *Balaban*.

An Examiner may only establish a *prima facie* case of obviousness when "the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). In asserting that the prior art "suggested" the claimed subject matter, however, an Examiner must realize that "the mere fact that the prior art may be modified in the manner suggested by the Examiner neither makes the modification prima facie obvious unless the prior art suggested the desirability of the modification." In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Moreover, the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." Id. The Federal Circuit has further stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." Id.

In response to Applicants' prior argument that the Examiner was picking and choosing features from different references in an attempt to construct a *prima facie* obviousness rejection, the Examiner notes in the Advisory Action dated August 13, 2004, that "both references are in the same field of endeavor." For the reasons noted above, this interpretation of *Blevins* is misplaced. Blevins is directed to a control template for process control applications, while *Balaban* is directed to storing bioinformatics data in a database. This failure of the Examiner to make out a *prima facie* case is sufficient reason alone to reverse the Section 103 rejection of claims 1 and 29, as well as the rejection of the claims which depend therefrom.

4. EVEN IF *BLEVINS* WERE TO BE COMBINED WITH *BALABAN*, THE RESULTING DEVICE WOULD NOT CONTAIN ALL FEATURES OF APPLICANTS' INVENTION AS RECITED IN CLAIM 1

The combination of *Blevins and Balaban*, even if it were suggested by other than hindsight, would not meet the recitations of claim 1 without substantial modifications being made to the resulting system. Specifically, the combination of *Blevins* and *Balaban* would fail to

provide "[a] method for managing biological information related to a biological experiment comprising: providing one or more identifiers related to the use of a probe array used to acquire the biological information; receiving a specification of an attribute for at least one of the one or more identifiers; generating a data template including at least one of the one or more identifiers, wherein the data template is configured to receive a value for each at least one identifier, said value representing the attribute specified for that identifier for the biological experiment; and receiving by the data template a value for the at least one identifier in accordance with the attribute specified for the identifier" as recited in claim 1 and "[a] computer program product, comprising: a template generator that generates a data template including one or more identifiers of a biological experiment with probe arrays, each identifying an attribute of the experiment; a value receiver that receives values for the identifiers in accordance with their attributes; and a data storage manager that stores the values in a data structure; wherein the values are based on one ore more experiments on one or more probe arrays." as recited in claim 29.

(a) BLEVINS FAILS TO TEACH THE CLAIM 1 LIMITATION DIRECTED TO RECEIVING A SPECIFICATION OF AN ATTRIBUTE FOR [AN] IDENTIFIER, AS ASSERTED BY THE EXAMINER

The Examiner asserts, as noted, that *Blevins* teaches "receiving a specification of an attribute for at least one of the one or more identifiers" as claimed. The recited "one or more identifiers" is preceded by the word "the," referring to the prior introduction of the term "one or more identifiers" in Applicants' claim. This is found in the prior element of claim 1, in which the "one or more identifiers" are claimed to be "related to the use of a probe array used to acquire the biological information." Thus, the claim term should be read as "*receiving a specification of an attribute for at least one of the one or more identifiers related to the use of a probe array used to acquire the biological information.*"

Blevins neither discloses, teaches nor suggests receiving a specification of an attribute for [an] identifier related to the use of a probe array used to acquire biological information. Rather, *Blevins* is directed to creating control templates that have attributes, methods, and graphical views associated therewith that can be selected by a user to generate design process control solutions and from which a user can create a unique display of a view such as an engineer's view, operator's view, controller's view, and the like, as noted above.

(b) BLEVINS FAILS TO TEACH THE CLAIM 1 LIMITATION DIRECTED TO GENERATING A DATA TEMPLATE THAT RECEIVES A IDENTIFIER VALUES REPRESENTING AN ATTRIBUTE SPECIFIED FOR THAT IDENTIFIER FOR THE BIOLOGICAL EXPERIMENT, AS ASSERTED BY THE EXAMINER

The Examiner also asserts that *Blevins* teaches "... generating a data template including at least one of the one or more identifiers, wherein the data template is configured to receive a value for each at least one identifier, said value representing the attribute specified for that identifier for the biological experiment ..." as recited in Applicants' claim 1.

For the reasons noted above, *Blevins* fails to teach or suggest providing a data template configured to receive Applicants' identifiers as claimed. In addition, this element of claim 1 explicitly recites that the values received by the data template represent an attribute "specified for that identifier for the biological experiment ..." (emphasis added). Since *Blevins* teaches only creating user-type-specific control templates for process monitoring and control systems, and neither teaches nor suggests managing information, particularly biological information, Applicants respectfully submit that *Blevins* also fails to teach this element of Applicants' claimed invention.

This interpretation of *Blevins* is supported by the teachings of *Blevins* cited by the Examiner in support of this contention. There, *Blevins* teaches that the data prompts are nothing more than conventional user interface prompts in the visual interface 220 which allows a user the processes the user wants to monitor or control with the control template the user is creating:

> The CPU 116 of the workstation 106 is used for the selection of data prompts causing the generation of display screens that enable creation, execution, and monitoring of process control programs and with the template generator 124 for the purpose of selecting display screens that allow creating and/or editing of control templates. The book 220 includes a title portion 222 and a selection portion 224. The title portion 222 provides the user with the name of the particular project, or book, that is currently selected or opened. The selection portion 224 provides a list of data prompts related to processes associated with the particular project that may be selected by a user to create the unique control template or modify an existing control template. It is understood that a user "selects" particular commands, functions or portions of the window 200 in any conventional windowing manner, such as by double clicking a mouse (not shown) on the prompts or by

entering a command key sequence on the user-interface device such as a keyboard shown as part of display 118. (*See*, Blevins col. 9, ln. 59 to col. 10 ln. 9; emphasis added.)

(c) BLEVINS FAILS TO TEACH THE CLAIM 1 LIMITATION DIRECTED TO RECEIVING BY THE DATA TEMPLATE A VALUE FOR THE AT LEAST ONE IDENTIFIER IN ACCORDANCE WITH THE ATTRIBUTE SPECIFIED FOR THE IDENTIFIER ..., AS ASSERTED BY THE EXAMINER

The Examiner asserts that *Blevins* teaches " ... receiving by the data template a value for the at least one identifier in accordance with the attribute specified for the identifier ..." as claimed. This assertion is also misplaced. *Blevins* fails to disclose, teach or suggest receiving a value for any identifier in accordance with an attribute specified for that identifier. In Applicants' claim, the receiving of the specification of the attribute and the receiving of a value in accordance with the specified attribute are two distinct steps, the value of the latter defined by the earlier-received specification. The Examiner has not addressed these two separate steps, essentially asserting that the generation of *Blevins* control template subsumes the two recited steps. This is incorrect. There is no receiving step as claimed which comprises receiving a value that is in accordance with a previously received specification of an attribute.

Furthermore, for the reasons noted above, the recited identifiers and attributes are nowhere taught nor suggested in *Blevins*.

(d) BLEVINS FAILS TO TEACH THE CLAIM 29 LIMITATION DIRECTED TO A TEMPLATE GENERATOR THAT GENERATES A DATA TEMPLATE WITH IDENTIFIERS OF A BIOLOGICAL EXPERIMENT, AS ASSERTED BY THE EXAMINER

The Examiner asserts that *Blevins* teaches "a template generator that generates a data template including one or more identifiers of a biological experiment with probe arrays." The Examiner relies on the generator 124 of *Blevins* described at column 7, lines 18-20, and the attributes as defined at column 7, lines 10-15 of *Blevins*. This understanding of *Blevins* is misplaced.

The generator 124 of *Blevins*, as noted, is used to generate control templates which include attribute functions for controlling a process and the methodology used for a particular

process control function, along with the control attributes, variables, inputs, and outputs for the particular function and the graphical views of the function as needed for the particular view. (*See*, Blevins, col. 7, lns. 10-17). For the variety of reasons discussed herein, such a control template does not include identifiers for a biological experiment. Furthermore, the control template of *Blevins* is not analogous to the data templates of Applicants' claimed invention.

(e) BLEVINS FAILS TO TEACH THE CLAIM 29 LIMITATION DIRECTED TO A VALUE RECEIVER THAT RECEIVES VALUES FOR THE IDENTIFIES IN ACCORDANCE WITH THEIR ATTRIBUTES AS ASSERTED BY THE EXAMINER

The Examiner asserts that *Blevins* teaches " ... a value receiver that receives values for the identifiers in accordance with their attributes ..." as recited in claim 29. For the reasons noted above, this assertion is misplaced. *Blevins* fails to disclose, teach or suggest receiving a value for any identifier in accordance with an attribute specified for that identifier. Furthermore, for the reasons noted above, the recited identifiers and attributes are nowhere taught nor suggested in *Blevins*.

Thus, for at least the reasons noted above, Applicants respectfully assert that, contrary to the Examiner's assertions, *Blevins* fails to teach those features of Applicants' invention recited in independent claims alleged by the Examiner. For at least this reason, Applicants respectfully assert that the Examiner has failed to support the Section 103 rejection of independent claims 1 and 29, and that each rejection should be reversed.

(F) BALABAN FAILS TO TEACH OR SUGGEST THAT WHICH IS MISSING FROM BLEVINS

Balaban teaches a database for organizing bioinformatics data. *Balaban* fails to teach that which is missing from *Blevins*. Specifically, *Balaban* neither discloses, teaches nor suggests any of the limitations of Applicants' method for managing biological information related to a biological experiment: "...providing one or more identifiers related to the use of a probe array used to acquire the biological information; receiving a specification of an attribute for at least one of the one or more identifiers; generating a data template including at least one of the one or more identifiers, wherein the data template is configured to receive a value for each at least one

identifier, said value representing the attribute specified for that identifier for the biological experiment; and receiving by the data template a value for the at least one identifier in accordance with the attribute specified for the identifier." Nor does *Balaban* disclose, teach or suggest Applicants' claimed "computer program product, comprising: a template generator that generates a data template including one or more identifiers of a biological experiment with probe arrays, each identifying an attribute of the experiment; a value receiver that receives values for the identifiers in accordance with their attributes; and a data storage manager that stores the values in a data structure; wherein the values are based on one ore more experiments on one or more probe arrays."

Thus, even of the references were to be combined as proposed by the Examiner, the resulting combination of *Blevins* and *Balaban* would fail to include all the elements of Applicants' invention as recited in Applicants' independent claims 1 and 29. Accordingly, Applicants respectfully assert that Applicants' independent claims 1 and 29, and claims 2-18 and 30-38 which depend therefrom, are patentable over the *Blevins* taken alone or in combination with *Balaban*.

B. OBVIOUSNESS REJECTIONS OF CLAIMS 20-28 AND 39-44

1. THE REJECTIONS

Claims 20-28 and 39-44 stand finally rejected under 35 USC 103(a) as being unpatentable over *Blevins*. Specifically, the Examiner asserts that *Blevins* substantially teaches Applicants' invention as recited in independent claims 20 and 39. The Examiner acknowledges, however, that *Blevins* fails to teach "this is a biological experiment." The Examiner nonetheless asserts because *Blevins* "teaches a particularly selected control template attribute such as temperature, pressures, and the line, to be further discussed below," this indicates that the attributes such as temperature and pressure are the parameters of the lab experiment. From this the Examiner concludes that it would have been obvious to one of ordinary skill in thee art at the time of the invention to modify the attributes in *Blevins* in order to conduct biological experiments as claimed.

2. THE EXAMINER HAS MISAPPREHENDED *BLEVINS*

The Examiner mistakenly interprets the reference to "lab personnel" and "lab workstations" in *Blevins* as referring to a some sort of laboratory and, as such, the control templates of *Blevins* are used to control laboratory experiments. For the reasons noted above, this is incorrect.

Blevins is directed to process monitoring and control systems and, in particular, to a system for creating control templates that have attributes, methods, and graphical views associated therewith that can be selected by a user to design process control solutions and from which a user can create a unique display of a view such as an engineer's view, operator's view, controller's view, and the like. (*See*, Blevins, col. 1, lns. 16-26.) Process control as defined in *Blevins* "involves the use of instruments, control devices and systems for measuring and manipulating control elements such as valves to maintain one or more process variables, such as temperature, pressure and flow, at target values selected to achieve a desired objective of a process including the ... operation of machines and equipment utilized in the process. Process control systems have widespread application in the automation of industrial processes such as those used in chemical, petroleum, and manufacturing industries, for example." (*See*, Blevins, col, 1, lns. 29-39.)

3. *BLEVINS* FAILS TO TEACH THE LIMITATIONS OF CLAIM 20 ASSERTED BY THE EXAMINER, LEAVING THE OFFICE ACTION WITHOUT A *PRIMA FACIE* REJECTION

In contrast to the Examiner's assertions, *Blevins* fails to disclose, teach or suggest a "method for managing biological experiment information generated through the performance of a biological experiment with probe arrays," as recited in Applicants' claim 20. Specifically, for the reasons set out above, *Blevins* fails to disclose, teach or suggest "receiving from a first user a selection of a first data template having a plurality of identifiers each identifying an attribute of the biological experiment;" "displaying the first data template to the first user in response to the selection;" and "receiving from the first user values for one or more of the identifiers of the first data template in accordance with the attributes identified by the one or more identifiers."

As noted, the Examiner relies solely on *Blevins* in support of this rejection. As such, because *Blevins* fails to disclose, teach or suggest the above limitations of Applicants invention as recited in claim 20, the Office Action fails to provide a *prima facia* rejection. Accordingly, the rejection should be reversed.

4. *BLEVINS* FAILS TO TEACH THE LIMITATIONS OF CLAIM 39 ASSERTED BY THE EXAMINER, LEAVING THE OFFICE ACTION WITHOUT A *PRIMA FACIE* REJECTION

In contrast to the Examiner's assertions, *Blevins* fails to disclose, teach or suggest a "computer implemented system for managing information of probe array experiments, as recited in Applicants' claim 39. Specifically, for the reasons set out above, *Blevins* fails to disclose, teach or suggest "a data template generator [that] generates at least one user-defined data template ... each defining attributes of a set of experiment identifiers, a data template being selected from the at least one user-defined data template by a user using the experiment manager, experiment identifiers being inputted using the experiment manager according to the selected data template, the inputted experiment identifiers being stored in the database as an experiment information file." (*See*, Applicants' claim 39, above.)

Hereto, the Examiner relies solely on *Blevins* in support of this rejection. As such, because *Blevins* fails to disclose, teach or suggest the above limitations of Applicants' invention as recited in claim 39, the Office Action fails to provide a *prima facia* rejection. Accordingly, the rejection should be reversed.

IX. CONCLUSION

For the reasons noted above, Applicants submit that the pending claims define patentable subject matter. Accordingly, Applicants request that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,

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Michael G. Verga
Reg. No. 39,410
Attorney for Applicants

APPENDIX A

CLAIMS ON APPEAL

1. A method for managing biological information related to a biological experiment comprising:

providing one or more identifiers related to the use of a probe array used to acquire the biological information;

receiving a specification of an attribute for at least one of the one or more identifiers;

generating a data template including at least one of the one or more identifiers, wherein the data template is configured to receive a value for each at least one identifier, said value representing the attribute specified for that identifier for the biological experiment; and

receiving by the data template a value for the at least one identifier in accordance with the attribute specified for the identifier.

2. The method of claim 1, further comprising:

storing the value for the at least one identifier in a data structure.

3. The method of claim 2, wherein:

the data structure is included in a database.

4. The method of claim 1, wherein:

the one or more identifiers comprise biological experiment identifiers and the data templates comprise a biological experiment data template.

5. The method of claim 1, wherein:

the one or more identifiers comprise sample identifiers and the data template comprises a sample data template.

6. The method of claim 1, wherein:

the data structure comprises an experiment information file for storing the information related to the biological experiment.

7. The method of claim 1, further comprising:

displaying, prior to receiving a value for the at least one identifier, the data template to a first user.

8. The method of claim 7, wherein:

the value is provided by the first user responsive to displaying the data template.

9. The method of claim 7, wherein:

the value is provided by the first user in accordance with a first type attribute.

10. The method of claim 9, wherein:

the first type attribute comprises one or more of the group consisting of a date attribute, time attribute, integer attribute, floating point data attribute, character string attribute, required attribute, or controlled attribute.

11. The method of claim 10, wherein:

the value is provided by the first user in accordance with a required attribute.

12. The method of claim 11, wherein:

the required attribute specifies that the value is either required or not required to be received.

13. The method of claim 10, wherein:

the value is provided by the user in accordance with a controlled attribute.

14. The method of claim 13, wherein:

the controlled attribute specifies that the value is to be one or more of a plurality of user-specified values specified by a second user.

15. The method of claim 14, wherein:

the first and second users are different users.

16. The method of claim 2, further comprising:

storing instrument information for at least one instrument in the data structure, wherein the instrument is included in an experiment related to the probe array.

17. The method of claim 2, further comprising:

storing image data in the data structure, wherein the image data is based, at least in part, on scanning of the probe array.

18. The method of claim 17, further comprising:

analyzing the image data to generate results data; and

storing the results data in the data structure.

19. The method of claim 18, further comprising:

tracking the value, the image data, and the result data.

20. A method for managing biological experiment information generated through the performance of a biological experiment with probe arrays, the method comprising the steps of:

receiving from a first user a selection of a first data template having a plurality of identifiers each identifying an attribute of the biological experiment;

displaying the first data template to the first user in response to the selection;

receiving from the first user values for one or more of the identifiers of the first data template in accordance with the attributes identified by the one or more identifiers; and

saving the values in a data structure.

21. The method of claim 20, wherein receiving a selection of a first data template comprises:

displaying a list of names of a plurality of data templates; and

receiving from the first user, a selection of one of the displayed list of names a name of the first data template.

22. The method of claim 21, wherein:

the plurality of data templates include one ore more default data templates.

23. The method of claim 21, wherein:

the list of names is displayed to the first user in a tree structure of a graphical user interface.

24. The method of claim 20, wherein:

the data structure includes an experiment information file.

25. The method of claim 24, wherein:

the experiment information file is included in a database.

26. The method of claim 20, further comprising:

generating the first data template based, at least in part, on a second user specifying the plurality of identifiers.

27. The method of claim 26, further comprising:

generating the first data template based, at least in part, on a second user specifying the attributes of the plurality of identifiers.

28. The method of claim 27, wherein:

the first and second users are different users.

29. A computer program product, comprising:

a template generator that generates a data template including one or more identifiers of a biological experiment with probe arrays, each identifying an attribute of the experiment;

a value receiver that receives values for the identifiers in accordance with their attributes; and

a data storage manager that stores the values in a data structure;

wherein the values are based on one ore more experiments on one or more probe arrays.

30. The computer program product of claim 29, wherein:

the identifiers include experiment identifiers and the data template includes an experiment data template.

31. The computer program product of claim 29, wherein:

the identifiers include sample identifiers and the data template includes a sample data template.

32. The computer program product of claim 29, wherein:

the data structure includes an experiment information file.

33. The computer program product of claim 29, wherein:

the template generator generates the data template in response to a first user specifying at least one of the one or more identifiers.

34. The computer program product of claim 29, wherein:

the template generator generates the data template in response to a first user specifying at least one attribute of the one or more identifiers.

35. The computer program product of claim 33, wherein:

the data template is selected by a second user.

36. The computer program product of claim 29, wherein:

the data storage manager further stores instrument information regarding at least one instrument in the data structure, wherein the instrument is included in the one or more experiment.

37. The computer program product of claim 29, wherein:

the data storage manager further stores image data in the data structure, wherein the image data is based, at least in part, on scanning of the one or more probe arrays.

38. The computer program product of claim 29, further comprising:

an analysis application that analyzes the image data to generate results data; and

wherein the data storage manager further stores the results data in the data structure.

39. A computer implemented system for managing information of probe array experiments, comprising:

a computer-readable storage medium;

a database;

a data template generator coupled to the computer-readable storage medium; and

an experiment manager coupled to the computer-readable storage medium and the data base,

wherein the data template generator generates at least one user-defined data template and stores the user-defined data template on the computer-readable storage medium, each user-defined data template defining attributes of a set of experiment identifiers, a data template being selected from the at least one user-defined data template by a user using the experiment manager, experiment identifiers being inputted using the experiment manager according to the selected data template, the inputted experiment identifiers being stored in the database as an experiment information file.

40. The system of claim 39, wherein:

instrument information is included in the experiment information file.

41. The system of claim 39, further comprising:

a data processor, coupled to the database, for acquiring experiment data and storing the experiment data as an experiment data file in the database, a data analyzer, connected to the database, for analyzing the experiment data, generating analyzed result files, and storing the analyzed result files in the database; and

a file manager for tracking the experiment information file, the experiment data file, and the analyzed result files.

42. The system of claim 41, wherein:

the experiment data file is an image file.

43. The system of claim 41, wherein:

the file manage tracks the experiment information file, the experiment data file, and the analyzed result files according to the file names.

44. A computer implemented system for managing information of probe array experiments, comprising:

a computer-readable storage medium having at least one default data table stored thereon;

a database;

a data template generator coupled to the computer-readable storage medium; and

an experiment manager coupled to the computer-readable storage medium and the database;

wherein the data template generator generates at least one user-defined data template and stores the user-defined data template on the computer-readable storage medium, each user-defined data template defining the attributes of a set of experiment identifiers, a data template being selected from the group consisting of the default data table and the user-defined data template by a user using the experiment manager, experiment identifiers being inputted using the experiment manager according to the selected data template, the inputted experiment identifiers being stored in the database as an experiment information file.